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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/674,824	Loerz et al.
Examiner	**Art Unit**
Shin-Lin Chen	1632

-- The MAILING DATE of this communication appears on th cover she t with th correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Sep 16, 2002

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-26 is/are pending in the applica

4a) Of the above, claim(s) 7, 13, and 17-26 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-6, 8-12, and 14-16 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of group I, claims 1-6, 8-12 and 14-16, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that groups I and III are related. The polynucleotide of group I encodes the protein of group III, and therefore, they have unity of invention. This is not found persuasive because the technical feature shared by groups I and III is the nucleic acid molecule in group I, i.e. a nucleic acid molecule encoding a protein comprising the amino acid sequence of SEQ ID No. 2, a nucleic acid molecule comprising the nucleotide sequence of SEQ ID No. 1 or a part thereof, or a nucleic acid molecule which hybridizes with the nucleic acid molecules set forth above. Block et al. (1996) discloses a Triticum aestivum soluble starch synthase cDNA sequence, GenEmbl Accession No. U48227, which is 100% identical to base 718 to 2271 of SEQ ID No. 1, and therefore contains a part of SEQ ID No. 1 and will hybridize to SEQ ID No. 1. Thus, no special technical feature is contributed over the prior art by the present application. Groups I and III do not relate to a single general inventive concept under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 7, 13 and 17-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claims 1-26 are pending and claims 1-6, 8-12 and 14-16 are under consideration.

Claim Objections

3. Claims 12 and 14-16 are objected to under 37 CFR 1.75(c) as being in improper form because they are multiple dependent claims. Claims 12, 15 and 16 depend on "one or more of claims 1-5" or "one or more of claims 8-11". See MEP. § 608.01(n). Accordingly, the claims 12 and 14-16 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "regulatory elements which ensure the synthesis of an untranslatable RNA in pro- or eukaryotic cells" in claim 10 is vague and renders the claim indefinite. The nucleic acid molecule encodes a protein having the function of a wheat starch synthase. It is unclear how a regulatory element ensures the synthesis of an untranslatable RNA when the nucleic acid molecule is linked in sense orientation to said regulatory element.

Claim 14 is vague and indefinite because it depends on nonelected claim 13. It is unclear what is intended to be claimed in claim 14.

6. Claim 16 recites the limitation "such a cell" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is unclear what cell is intended for 'such a cell".

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6, 8-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on a nucleic acid molecule comprising part of nucleotide sequence of SEQ ID No. 1 and nucleic acid molecule which hybridizes with nucleic acid encoding the amino acid sequence of SEQ ID No. 2 or nucleic acid comprising the nucleotide sequence of SEQ ID No. 1 or a part thereof, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase, a vector comprising said nucleic acid molecule, a host cell

transformed with said nucleic acid molecule or said vector, and a process for producing a protein by using said host cell.

The specification only discloses a polynucleotide sequence of SEQ ID No. 1 and the amino acid sequence (SEQ ID No. 2) encoded by SEQ ID No. 1. The claims encompass any nucleic acid molecule comprising part of nucleotide sequence of SEQ ID No. 1 and nucleic acid molecule which hybridizes with nucleic acid encoding the amino acid sequence of SEQ ID No. 2 or nucleic acid comprising the nucleotide sequence of SEQ ID No. 1 or a part thereof, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase.

The claims read on adding unknown nucleotide sequence at 5', 3' ends and/or within the nucleotide sequence of SEQ ID No. 1, or deleting or substituting the nucleotide sequence of SEQ ID No. 1. A part of SEQ ID No. 1 can be a nucleotide to several hundreds of nucleotides, and a nucleic acid molecule comprising a part of SEQ ID No. 1 can be any gene, either known or unknown and unidentified gene. The scope of the claims include various known, and unknown and unidentified genes that either encodes or not encodes a polypeptide. The structures of the those various genes have not been disclosed and there is no known or disclosed correlation between function and structure of the non-described regulatory elements and untranslated regions of the gene. Furthermore, there is no additional disclosure of physical and/or chemical properties. The specification also fails to provide the structural features of the nucleic acid molecule encoding a protein having a wheat starch synthase activity. Thus, one skilled in the art

at the time of the invention would not be able to envision all the nucleic acid molecules encompassed in the claims.

The claims also encompass various nucleic acid molecules encoding a genus of numerous structural variants of the amino acid sequence of SEQ ID No. 2 having a starch synthase activity, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification fails to provide the structural features of the variant proteins. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the amino acid sequence of SEQ ID No. 2 as disclosed in the present application is insufficient to describe the genus. The nucleotide sequence of SEQ ID No. 1 encoding the amino acid sequence of SEQ ID No. 2 is insufficient to describe the claimed nucleic acid molecules.

This limited information is not sufficient to reasonably convey to one skilled in the art that applicants were in possession of the claimed nucleic acid molecules, vectors, host cells, and a process of using said nucleic acid molecule, vector, and host cell. Thus, it is concluded that the written description requirement is not satisfied for the nucleic acid molecules, such as genes, as claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieve regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the disclosed nucleotide sequence of SEQ ID No. 1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

9. Claims 1-6, 8-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule comprising the sequence of SEQ ID No. 1, does not reasonably provide enablement for any nucleic acid molecule comprising part of nucleotide sequence of SEQ ID No. 1, any nucleic acid molecule which hybridizes with nucleic acid encoding the amino acid sequence of SEQ ID No. 2 or nucleic acid comprising the nucleotide sequence of SEQ ID No. 1 or a part thereof, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase, a vector comprising said nucleic acid molecule, a host cell transformed with said nucleic acid molecule or said vector, and a process of using said nucleic acid molecule, vector, and host cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to a nucleic acid molecule comprising SEQ ID No. 1 or a part thereof, a nucleic acid molecule encoding a protein comprising the sequence of SEQ ID No. 2, a nucleic acid molecule which hybridizes with said nucleic acid molecule, and a nucleic acid molecule whose sequence deviates from the sequence of nucleic acid molecules set forth above due to degeneracy of genetic code, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase, a vector comprising said nucleic acid molecule, a host

cell, such as a plant cell, transformed with said nucleic acid molecule or said vector, and a process for producing a protein by using said host cell. Claim 5 specifies the nucleic acid molecule is a RNA molecule. Claim 6 specifies a nucleic acid molecule that hybridizes with the nucleic acid molecules set forth above. Claims 10 and 11 specify the nucleic acid molecule is linked in sense and antisense orientation to regulatory elements that ensure synthesis of an untranslatable RNA in host cells, respectively.

The specification only discloses a polynucleotide sequence of SEQ ID No. 1 and the amino acid sequence (SEQ ID No. 2) encoded by SEQ ID No. 1. The claims encompass any nucleic acid molecule comprising part of nucleotide sequence of SEQ ID No. 1 and nucleic acid molecule which hybridizes with nucleic acid encoding the amino acid sequence of SEQ ID No. 2 or nucleic acid comprising the nucleotide sequence of SEQ ID No. 1 or a part thereof, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase, a vector comprising said nucleic acid molecule, a host cell containing said vector, and a process of using said nucleic acid molecule or vector to produce a transgenic plant cell or a process of using said host cell to produce a protein.

The claims read on adding unknown nucleotide sequence at 5', 3' ends and/or within the nucleotide sequence of SEQ ID No. 1, or deleting or substituting the nucleotide sequence of SEQ ID No. 1. A part of SEQ ID No. 1 can be a nucleotide to several hundreds of nucleotides, and a nucleic acid molecule comprising a part of SEQ ID No. 1 can be any gene, either known or unknown and unidentified gene. The scope of the claims include various known, and unknown

and unidentified genes that either encodes or not encodes a polypeptide. The claims also encompass various nucleic acid molecules encoding a genus of numerous structural variants of the amino acid sequence of SEQ ID No. 2 having a starch synthase activity. The specification fails to provide adequate guidance and evidence whether the claimed nucleic acid molecules encode proteins having the function of a wheat starch synthase and how one skilled in the art would distinguish the nucleic acid molecules encoding a starch synthase from those not encoding a starch synthase. The specification also fails to provide adequate guidance and evidence that a nucleic acid molecule hybridizing with nucleic acid encoding the amino acid sequence of SEQ ID No. 2 or nucleic acid comprising the nucleotide sequence of SEQ ID No. 1 or a part thereof would have the function of a wheat starch synthase.

The claims encompass nucleic acid molecules encoding various structural variants of SEQ ID No. 2 and numerous unknown and unidentified proteins. It was known in the art that the amino acid sequence of a polypeptide determines its structural and functional properties (including half-life), and predictability of which amino acid(s) can be removed from or added to a polypeptide's sequence and still result in similar or higher activity or result in stabilization of the protein is extremely complex, and well outside the realm of routine experimentation. Rudinger, 1976 (Peptide Hormones, Parsons, University Park Press, Baltimore, p. 1-7) points out that "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study" (e.g. p. 6). Kaye et al., 1990 (Proc. Natl. Acad. Sci. USA, Vol. 87, pp. 6922-

6926) discloses that a single amino acid substitution results in a retinoblastoma protein defective in phosphorylation and oncoprotein binding (e.g. title). Skolnick et al., 2000 (Trends in Biotech, Vol. 18, p. 34-39) states "Sequence-based methods for function prediction are inadequate because of the multifunctional nature of proteins. However, just knowing the structure of the protein is also insufficient for prediction of multiple functional sites. Structural descriptors for protein functional sites are crucial for unlocking the secrets in both the sequence and structural-genomics projects" (e.g. abstract). Skolnick further states that "Knowing a protein's structure does not necessarily tell you its function" and "Because proteins can have similar folds but different functions, determining the structure of a protein may or may not tell you something about its function" (e.g. p. 36, box 2). In view of the lack of detailed information regarding the structural and functional requirements of the polypeptide of SEQ ID No. 2 and its variants, and the unpredictability of polypeptide function from mere amino acid sequence, it would be unpredictable whether the polypeptides encoded by the claimed nucleic acid molecules would have the function of a wheat starch synthase. In view of such, one skilled in the art at the time of the invention would not know how to use the claimed nucleic acid molecules encoding various structural variants of SEQ ID No. 2, and numerous known and unknown polypeptides.

Therefore, it is concluded that based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, and the breadth of the claims that it would require a skilled artisan at the time of the invention undue experimentation to practice over the full scope of the invention claimed.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Block et al., 1996, GenEmbl Accession No. U48227 (computer printout, page 11, 12).

Claims 1-3, 5 and 6 are directed to a nucleic acid molecule comprising SEQ ID No. 1 or a part thereof, a nucleic acid molecule encoding a protein comprising the sequence of SEQ ID No. 2, a nucleic acid molecule which hybridizes with said nucleic acid molecule, and a nucleic acid molecule whose sequence deviates from the sequence of nucleic acid molecules set forth above due to degeneracy of genetic code, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase. Claim 5 specifies the nucleic acid molecule is a RNA molecule. Claim 6 specifies a nucleic acid molecule that hybridizes with the nucleic acid molecules set forth above.

Block teaches a wheat Triticum aestivum soluble starch synthase mRNA sequence, GenEmbl Accession No. U48227, which is 100% identical to base 718-2771 of SEQ ID No. 1. The sequence of GenEmbl Accession No. U48227 comprises a part of nucleotide sequence of SEQ ID No. 1 and will hybridize to nucleotide sequence of SEQ ID No. 1. Thus, claims 1-3, 5 and 6 are anticipated by Block.

12. Claims 1-6, 8, 9, 12 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Block, 1997 (WO 97/45545, IDS-AF, and computer printout, page 5, 6).

The claims are directed to a nucleic acid molecule comprising SEQ ID No. 1 or a part thereof, a nucleic acid molecule encoding a protein comprising the sequence of SEQ ID No. 2, a nucleic acid molecule which hybridizes with said nucleic acid molecule, and a nucleic acid molecule whose sequence deviates from the sequence of nucleic acid molecules set forth above due to degeneracy of genetic code, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase, a vector comprising said nucleic acid molecule, a host cell, such as a plant cell, transformed with said nucleic acid molecule or said vector, and a process for producing a protein by using said host cell. Claim 5 specifies the nucleic acid molecule is a RNA molecule. Claim 6 specifies a nucleic acid molecule that hybridizes with the nucleic acid molecules set forth above.

Block teaches a wheat soluble starch synthase cDNA sequence (SEQ ID No. 1 of WO 97/45545), Geneseq Accession No. AAV01527, which is 100% identical to base 533-2771 of SEQ ID No. 1. The sequence of Geneseq Accession No. AAV01527 comprises a part of nucleotide sequence of SEQ ID No. 1 and will hybridize to nucleotide sequence of SEQ ID No. 1. Block teaches a nucleic acid molecule comprising SEQ ID No. 1 or corresponding RNA sequence, a nucleic acid molecule encoding a protein comprising the sequence of SEQ ID No. 2, a nucleic acid molecule which hybridizes with said nucleic acid molecule, and a nucleic acid molecule whose sequence deviates from the sequence of nucleic acid molecules set forth above

due to degeneracy of genetic code, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase, a vector comprising said nucleic acid molecule, a host cell, such as a plant cell, transformed with said nucleic acid molecule or said vector, a transgenic plant cell, and a process for producing a protein by using said host cell or a process of making said transgenic plant cell (e.g. abstract, p. 63-65). Thus, claims 1-6, 8, 9, 12 and 14-16 are anticipated by Block.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.